Report on
RESEARCH COMPLIANCE

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News and Analysis for Colleges, Universities, AMCs and Other Non-Federal Entities

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Amid Time of Uncertainty, Proposed NIH Grant Support Index Adds to the Anxiety

Research compliance officials and investigators nervous about possible cuts to indirect cost rates and reductions in NIH funding have a new worry to ponder: the grant support index (GSI), a controversial methodology NIH may implement as early as September in an effort to stretch its funding.

The GSI is likely to target institutions' entrenched and older grant "rain-makers" and some labs with heavy NIH support. It would subject single principal investigator (PI) awards to a lifetime cap of three Research Project Grants (R01s). R01s are PI-initiated awards. NIH data show the average R01 is $458,000. NIH then plans to rechannel those funds.

As a result of imposing the GSI, "We are estimating over time at least $500 million and perhaps as much as $650 million [in funds] could be freed up and that potentially could translate into as many as 1,500 or 1,600 new awards," Michael Lauer, NIH deputy director for extramural research, said in a May 2 call with stakeholders. He did not specify the number of years the estimate was based on.

As the saying goes, the devil is in the details, and NIH officials have said that the policy "is a work in progress." Much is yet to be determined, such as how to handle co-PIs, subawardees, large collaborative projects and networks that provide care in addition to performing studies.

Still, agency leaders have affirmed that NIH is set on using a framework that calls for no further funding after a GSI score of 21, unless the PI can find a way to accept a new award and stay under that total.

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'Nothing Short of Appalling:' Inaction by HHS Oversight Agencies Sets off Alarms

So far this year, the HHS Office of Research Integrity (ORI) has not issued any findings of research misconduct, marking nearly 12 months since the last finding was issued.

ORI, which has been beset by staff turmoil and turnover since the arrival in December 2015 of Director Kathryn Partin, historically has made 12-15 findings of fabrication, falsification and plagiarism per year *(RRC 1/17, p. 1)*.

But it's not the only federal research watchdog agency that has outwardly slowed down or ceased its enforcement efforts. The HHS Office for Human Research Protections (OHRP), which safeguards the millions of people enrolled in hundreds of thousands of clinical trials, has not posted a determination letter in eight months; these letters are the vehicle for holding institutions responsible for following 42 CRF Part 46, also known as the Common Rule.

Sen. Chuck Grassley, R-Iowa, and leaders in the ethical conduct of research contacted by *RRC* are expressing alarm at the lack of enforcement and other actions by these unique, key oversight agencies. The new incoming HHS assistant secretary for

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health must focus on these offices and correct problems, they say, arguing that to do nothing may result in lasting damage.

"It is nothing short of appalling that the activities of two leading oversight agencies for research conducted with U.S. federal funds have ground to a halt," medical ethicist Ruth Macklin told *RRC*.

Macklin and others point out that the declines in activity by both agencies are not accompanied by a corresponding decline in lack of problems for them to tackle—quite the opposite.

"The paucity or absence of responses from these agencies is in direct opposition to what we have learned about an increase in cases of scientific misconduct—to which ORI responds—and a series of failures to obtain informed consent, as required by the federal regulations, [which is] the job of OHRP," Macklin said.

Macklin maintained there are "numerous cases that should be addressed by these two federal oversight agencies."

RRC has previously documented problems at both OHRP and ORI, but they have intensified in recent months, particularly at ORI (for details on ORI, see box, p. 3). Money doesn't seem to be at the root of any problems. Both agencies have received stable levels of funding over the years—approximately $8.5 million for ORI and $6.5 million for OHRP. The President's FY 2018 budget, released May 23, calls for the same amount for both agencies.

According to the reporting structure at HHS, both ORI and OHRP are under the Office of the Assistant Secretary for Health (ASH). Donald Wright is currently the acting ASH, a position he has held during the various vacancies and since the resignation of Karen DeSalvo, the prevision OASH. The position is a political one that requires Senate confirmation. DeSalvo was never confirmed but served in an acting capacity as she was already a federal employee.

President Trump announced his intention to nominate Brett Giroir, former CEO of the Texas A&M Health Science Center, to be the new ASH (*RRC 5/14/17*). As of *RRC*'s deadline, the nomination had not been posted on the Senate's website as formally submitted.

Determination letters issued by OHRP are the main vehicle the federal government has for communicating the appropriate conduct of human research trials, both to the public and the regulated institutions and investigators. In years past, OHRP occasionally published correspondence it had with institutions.

Last year OHRP issued 15 determination letters, a number that had set a record low in 2010. In 2015, however, OHRP only issued five letters. From 2007-2009, OHRP issued an average of 35 letters, down from a high of 86 in 2006 and a peak of 146 in 2002. The decline coincided with the arrival in 2008 with Director Jerry Menikoff; the agency told *RRC* he prefers informal means of resolving noncompliance allegations *(RRC 3/11, p. 1)*.

The letters are the product of investigations that began years earlier. Fewer investigations lead to fewer letters and vise-versa. The letters reflect OHRP findings from investigations that result from complaints, called "for cause," and those stemming from an oversight review that may or may not include a site visit, called "not-for-cause."

Asked why OHRP hasn't published any letters so far this year, and none since October, an agency spokeswoman said simply, "There have been no determination letters to publish since October 2016."

RRC asked whether the lack of letters could be seen as a sign that enforcement and compliance is not a priority for the agency. "OHRP staff has been very busy, particularly with the revised Common Rule," she said. The revised Common Rule was published in January, following a process that began in 2011. It is now under review by the Trump Administration (see story, p. 5).

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In response to a request from *RRC*, OHRP provided the following data on its investigations for the last three years:

◆ 2014: Opened seven for-cause, closed four. Opened four not-for-cause, closed four.

◆ 2015: Opened five for-cause; closed three. Opened three not-for-cause, closed two.

◆ 2016: Opened four for-cause, closed nine. Opened five not-for-cause, closed six.

◆ 2017 to date: Opened four for-cause, closed none. Opened one not-for-cause, closed none.

Beyond ensuring compliance by individual institutions, OHRP's letters provide insights and best practices that can prove educational for others. For example, in February 2016, OHRP sent a letter to University of Texas at San Antonio (UTSA) describing two instances of non-compliance. OHRP said the IRB had violated federal human subjects regulations by giving the go-ahead for NIH-funded studies about which it had requested but not yet received "substantive information or information necessary to make the required determinations for approval" *(RRC 4/16, p. 1)*.

UTSA told *RRC* that correspondence with OHRP on this issue had begun in 2012.

The agency has not availed itself of the other options to provide specific direction and guidance to institutions and investigators beyond determination letters. For example, the agency does not act on the recommendations and proposed guidance documents developed by its hard-working advisory panel, the Secretary's Advisory Committee on Human Research Protections (SACHRP).

Instead, Menikoff has suggested that SACHRP members publish their work on their own, stating that

ORI Inaction a Worry 'For All Scientists'

RRC first reported on the recent turmoil within the HHS Office of Research Integrity (ORI) in 2016, but has documented upheaval at the agency for years. However, the situation has reached a new low.

ORI is likely to go close to an entire year without any findings, compared to the typical number of a dozen or more per year. The other research oversight agency in HHS, the Office for Human Research Protections, is also showing evidence of an enforcement slowdown (see story, p. 1).

Determinations by ORI that fabrication, falsification or plagiarism in Public Health Service-funded research have occurred can result in debarment of investigators, as well as the imposition of supervisory plans. ORI can also require sanctioned investigators, whose names and misdeeds are published in the *Federal Register*, to retract papers containing errors.

ORI has been roiled by vacancies and lack of leadership for nearly a decade. When the current director, Kathryn Partin, was hired in December 2015, the job had been open since David Wright resigned in March 2014, after just two years. When he quit, Wright publicly lambasted HHS for causing "dysfunction" at ORI *(RRC 4/14, p. 1)*.

During these periods ORI continued to churn out misconduct findings, anchored by John Dahlberg. He retired from the No. 2 slot at ORI two years ago after being with the agency since its founding in 1992.

Under Partin's reign, however, ORI's investigative division has seen departures of many workers, and ORI's director of the Division of Education also left *(RRC 2/17, p. 1)*.

Distraught ORI staff have shared their concerns with *RRC* anonymously because they fear for their jobs and have been unable to secure others. The entire federal government is essentially under a job freeze. Investigative staff have written letters and emails to HHS leaders about Partin and met with both agency leaders and with members of Grassley's staff. To date they have received no help, ORI staff say.

ORI's policy is not to discuss personnel matters, and officials have not commented on staff complaints about Partin. After *RRC* reported that ORI had ended 2016 with a record low of six findings, Partin explained to the website Retraction Watch that several of ORI's current cases are "extremely large and complicated." She said ORI was bringing on new investigators, but staff have told *RRC* that these individuals are unqualified and are adding to their inability to close cases.

Today ORI is "critically short of scientist-investigators to pursue findings," due to "poor management and support for ORI by [HHS leadership] in the past, current internal divisions at ORI and subsequent staff departures" Wright said.

Given the continued lack of findings since August, fears of lasting detrimental impact are growing, Wright told *RRC*.

Published findings "have a deterrent effect on future misconduct, I believe," Wright said. "Institutions also look to ORI findings to validate and support their own investigations and institutional findings. The failure of ORI to move forward expeditiously with

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guidance has little value because it doesn't carry the legal authority that regulations do *(RRC 8/14, p. 1)*.

Data on OHRP's activities leads to many questions, said Macklin.

"Short staffing and other personnel difficulties at these oversight agencies may be part of the explanation," Macklin said. "But in an era when the highest levels of government are seeking to weaken, undercut or eliminate a wide variety of federal regulations, I fear that the system designed to protect the human subjects of biomedical research is at risk of collapse."

OHRP's inaction was highlighted in two books published in 2015, which both concluded that, as a result, the IRB system nationally was beset by inconsistencies and labored with little accountability *(RRC 5/15, p. 1)*.

One of OHRP's harshest critics is a former member of its staff—Michael Carome, MD, who now heads the Health Research Group of Public Citizen, which he joined in 2011. Carome was OHRP's director of regulatory affairs upon his retirement from the agency, having served as its director of oversight compliance among other positons during several decades with the federal government.

Carome expressed outrage that OHRP has released no letters since October.

"From Public Citizen's vantage point, it is clear that OHRP has repeatedly abused the agency's discretion under its existing compliance oversight policies by refusing to open formal compliance oversight investigations into multiple substantive complaints of material violations of federal regulations and ethical principles related to the protection of human subjects," Carome said. "The agency's leadership seems to look for excuses to avoid opening investigations and to be more interested in protecting research institutions rather than protecting human subjects."

In the last four years alone, Public Citizen has asked OHRP to investigate four clinical trials on the basis that they are unethical, and to take action against the University of Minnesota, whose human subjects protections

ORI Inaction a Worry 'For All Scientists', continued

warranted findings may encourage [accused investigators] and their counsel to delay settling cases or to decline to communicate at all with ORI in hopes that the problem will go away."

Sen. Charles Grassley, R-Iowa, gave a speech on the Senate floor asking HHS to get to the bottom of Wright's complaints after he resigned, a call he repeated in an email to *RRC*.

Proper functioning of ORI is essential, Grassley said. "This office has to function well for the integrity of tax dollars and patient benefit. The new secretary of the Department of Health and Human Services should make sure the office is looking for waste, fraud and abuse at its fullest capacity," he said in an email.

In addition to his long-term interest in research integrity, Grassley became more involved when a researcher in Iowa fabricated results in an HIV vaccine trial, leading to his criminal prosecution and the return of NIH funds *(RRC 8/15, p. 1)*.

Before his resignation, Wright testified before the Presidential Commission on the Study of Bioethical Issues that ORI had begun receiving more than 400 complaints a year of possible misconduct, a doubling from the past.

This increase makes ORI's mission all the more critical, said Ferric Fang, director of the Harborview Medical Center Clinical Microbiology Laboratory at the University of Washington School of Medicine, who also researches misconduct in science.

ORI's lack of findings "is certainly concerning, as there has been a steady rise in allegations, inquiries and investigations reported to the ORI over the past decade," Fang told *RRC*. He noted that the recent National Academy of Science report on research integrity stressed that ORI, along with the Office of Inspector General at the National Science Foundation, "play an essential role in addressing research misconduct" *(RRC 5/17, p. 1)*.

It is "reasonable" to fear that "a weakened ORI could encourage institutional inaction with regard to research misconduct," Fang said.

"The problems you describe are very disconcerting," agreed Arturo Casadevall, MD, chair of molecular microbiology and immunology at Johns Hopkins Bloomberg School of Public Health, in an email to *RRC*. Casadevall is also the founding editor of *MBio*, an open access journal, and frequently an author and researcher with Fang on misconduct, reproducibility and related issues.

"The ORI is a critically important institution for the integrity of science and any dysfunction involving that office should be of great concern to all scientists," he said.

program was the subject of enhanced state oversight *(RRC 7/15, p. 6)*. In each case, OHRP has not done so, Carome said.

Lois Shepherd, professor of biomedical ethics, law and public health sciences at the University of Virginia, also expressed concern and wondered whether OHRP would ever regain the enforcement muscle it seemed to have lost in recent years.

"This is an alarming trend, and we need to be asking what it is going to take to reverse it," said Shepherd. "Does OHRP need more funding and staffing? Better leadership? More independence? Certainly questions remain about OHRP's independence from NIH after the fallout over the SUPPORT study. OHRP was bludgeoned during that conflict."

SUPPORT stands for the Surfactant, Positive Pressure, and Oxygenation Randomized Trial, which OHRP in 2013 determined was conducted without appropriate disclosure to the parents of premature infants of all foreseeable risks, including death.

But NIH, which funded the multicenter trial, opposed the finding, leading to an unpreceded debate in the academic literature with dueling essays written by NIH Director Francis Collins himself (and coauthors, along with signatories) and by Macklin and Shepherd (and their signatories).

This study was termed "standard of care research," a loose concept closely aligned, if not identical, to comparative effectiveness research.

OHRP ultimately backed off, holding instead a meeting on standard of care research, followed by the publication of proposed guidance on the topic *(RRC 12/14, p. 1)*.

But OHRP has never issued final guidance, and the final Common Rule purposely does not address comparative effectiveness research. The preamble to the rule notes that draft guidance was issued (but doesn't mention that final guidance hasn't been).

The public scuffle left an impact on OHRP: In 2014 it opened only one investigation.

Guidance on Consent Called Lacking

OHRP's lack of direction on comparative effectiveness studies is a significant source of worry, Shepherd added.

"I'm especially concerned about the lack of enforcement actions—and guidance—coming out of OHRP on informed consent in comparative effectiveness studies," Shepherd told *RRC*. "Studies are being conducted and results published without the required consent of subjects, and even though results are published in top journals and the lack of consent is freely acknowledged, nothing appears to be happening at the top level to issue corrections."

The value of OHRP's determination letters, when they are issued, is that they communicate the "visible and public corrections" that OHRP asks institutions to make, said Shepherd. Along with guidance, these "are necessary to clarify the standards for IRBs to follow, especially on what the regulations require in terms of consent for new forms of research."

Shepherd also spoke of how OHRP actions are needed to support IRBs, given they are "generally internal organs and are overwhelmed" and argued that the "case law on research injury is undeveloped and therefore little help."

"We really have to have a strong, independent federal agency looking out for human subjects," Shepherd said. "We have to have a system of checks and balances." ✧

Surprise! New Common Rule Now Under Review; Outcome Uncertain

Institutions that waited nearly the entire Obama administration for a revised Common Rule governing human subjects research are going to have to continue being patient.

A final rule revamping 45 CFR Part 46, also known as the Common Rule, was issued on Jan. 19, the second-to-last day of President Obama's term in office *(RRC 2/17, p. 1)*. As published, the rule has the same effective date and implementation date (or compliance date), Jan. 19, 2018, one year from issuance, for most requirements.

Publication of the rule seemingly ended a protracted regulatory process that began in July 2011, when HHS and other agencies issued an advance notice of proposed rule making. The final rule contained a number of provisions that arguably could ease the load for investigators and institutional review boards (IRBs), such as changes to exempt categories and an allowance to stop reviewing some research.

But now the rule has gotten caught up in a "regulatory freeze" imposed by President Trump, and there is little information about its fate.

In the meantime, questions that the complicated Common Rule sparked have continued to grow, as a talk by an official with the Office for Human Research Protections (OHRP) at a recent meeting of the Federal Demonstration Partnership (FDP) showed. OHRP is the lead agency in the government charged with overseeing the conduct of human subjects research trials.

On the day he was inaugurated, President Trump signed an executive order implementing a hiring freeze,

as well as a regulatory freeze delaying the effective date of regulations that have been published but not yet taken effect to no earlier than March 21, 2017, which was 60 days from the date of the order (*RRC 2/3/17*).

Agencies were also told to withdraw any regulations that had not yet been published and that, in the future, "for every one new regulation issued, at least two prior regulations [must] be identified for elimination."

As explained in subsequent memorandums issued by the Office of Management and Budget (OMB), the purpose of the delay was to allow for "reviewing questions of fact, law, and policy 'as permitted by applicable law.'"

The review is to identify costs in new or proposed regulations and to identify ways to offset them. Agencies were also instructed to "consider postponing the effective date beyond 60 days where appropriate."

Even though the release date for the final Common Rule put it in the freeze/review period, the 2018 effective date was believed to mean it would likely be safe from any serious scrutiny. That argument was bolstered by the fact that the version that was ultimately released lacked many of the provisions the research community considered onerous. In addition, the Common Rule was not highlighted as a regulation that Congress wanted to repeal and, in its scaled-back final form, seemed palatable to the regulated community *(RRC 2/17, p. 1)*.

Implementation Could Be Delayed

It came as a surprise, then, when OHRP officials in mid-May said that the administration was indeed reviewing the new Common Rule and that the implementation date could be delayed.

However, some of the statements were conflicting and left institutions without definitive answers on issues that go beyond just the implementation date.

Word of the review first came May 12 when BNA's *Life Sciences Law & Industry Report* quoted Ivor Pritchard, senior advisor to OHRP Director Jerry Menikoff, who spoke at an industry meeting in Detroit. According to the report, Pritchard said OHRP was "basically in a holding pattern until they've had a chance to understand the provisions of the newly revised rule and recognize where there is latitude for new policy making."

He was also quoted as saying administration officials have not yet "decided whether they want to go forward with the rule at all," and that the implementation date could be delayed.

The following day, Irene Stith-Coleman, OHRP director of the Division of Policy and Assurances, spoke at the FDP meeting and answered questions prompted by Pritchard's comments after her formal presentation.

Stith-Coleman said OHRP is "operating under the assumption" that the 2018 date will hold "until we hear otherwise. And I can assure you, when we hear it, you're gonna hear it," she told the audience.

Asked when the review might be concluded, Stith-Coleman said, "I wish I had a crystal ball, but I don't. I don't know." She added that OMB and HHS, as well as other agencies, might be involved in the review.

Confusion Among the Questions

One thing was clear without need of a crystal ball: audience members had many questions, some of which evidenced confusion. For example, one questioner noted that the final rule does away with the "box" on assurances that indicates institutions will voluntarily apply the Common Rule and/or its subparts to non-HHS funded research, which allows OHRP to have jurisdiction over compliance. He asked whether the absence of the box (or boxes; there are two) meant that the Common Rule automatically applied to non-HHS funded human subjects research. The opposite is true.

"Once the box disappears, OHRP will have no enforcement authority over non-HHS" supported or conducted human subjects research, Stith-Coleman said.

In response to another query, Stith-Coleman said OHRP would not have jurisdiction over exempt research unless it is of the type that is subject to limited IRB review. But she added that if research was wrongly declared exempt, OHRP could take an enforcement action.

One questioner wondered what an institution's responsibilities are for oversight of expedited trials, given that the final rule doesn't require continuing review. Should the institution require notification that a trial is over or require a final report, she asked.

Another area of concern expressed by an audience member is that the rule removes the requirement for IRBs to review grant applications, but this currently is a mandate from NIH. Still another person said he understood that some studies could undergo limited IRB review, but that there was no information as to what that entails.

Stith-Coleman said OHRP would provide compliance materials in the future.

"We are hoping to put out guidance on a number of provisions, certainly new provisions as well as update our existing guidances. So we will be busy, are busy," she said.

Universities and other NIH grantees are also busy working toward implementation of the Common Rule's single IRB requirement for multisite trials

because, for them, the policy goes into effect in September *(RRC 1/17, p. 3)*.

NIH decided to go ahead with this requirement while the revised Common Rule was still being drafted.

Awardees of funding from the other dozen or so agencies that also require adherence to the Common Rule will have until Jan. 19, 2020 or later, depending on the outcome of the administration's review, to comply.

Link to Stith-Coleman's slides:
http://tinyurl.com/llo5vxp ✧

Former Medical College Grants Specialist Faces Prison for Theft

Carolyn McCain-Davis, 54, worked as a grant development specialist at a medical college in Tennessee for more than a decade, but, by her own admission, she also was developing a healthy balance in her bank account by stealing funds over the past several years.

Later this summer she will be sentenced after pleading guilty to embezzling at least $133,000 from Meharry Medical College (MMC) in Memphis. According to a charging document, MMC unknowingly issued approximately 32 checks for a total of $66,500 to McCain-Davis "and companies created, owned, controlled or operated" by her.

McCain-Davis' duties from April 2005 through August 2013 "included preparing and approving invoices, and processing payment requests relating to MMC's employees and vendors," according to court documents.

At her sentencing scheduled for August 9, McCain-Davis could receive up to a 10-year prison term and a $250,000 fine, according to a May 8 announcement of the plea agreement by the U.S. attorney's office for the Middle District of Tennessee. She could also receive "supervised release of not more than three years."

As part of her plea arrangement, McCain-Davis admitted that she created "false invoices" and then "personally approved" payment to herself and "close rela-

OCR Snags Another Academic Health System

Over the past several years, HIPAA-covered entities (CEs), especially academic health systems, have been paying an increasingly heavy price for their non-compliance, and May was no exception. On May 10, the HHS Office for Civil Rights (OCR) announced a $2.4 million settlement with Memorial Hermann Health System, the teaching affiliate of McGovern Medical School at UTHealth.

OCR alleged that the health system violated HIPAA when it issued a press release in 2015 following the arrest of a patient at one of its Ob-Gyn clinics who presented a fraudulent driver's license. The system did not admit to any wrongdoing, but agreed to make the payment and follow a two-year corrective action plan that has minimal requirements.

Unlike nearly all of OCR's past settlements, the agency did not cite the system for any other possible violations, such as a failure to conduct a security risk analysis. That made the size of the settlement all the more surprising. Yet it is not the largest paid by a CE; the record of $5.5 million is actually held by two organizations—Memorial Healthcare System of Florida and Advocate Health Care of Illinois.

Before that record was set, Feinstein Institute for Medical Research held the distinction of having paid the highest amount by a single entity. An investigation triggered by the theft of an unencrypted laptop led to a $3.9 million settlement *(RRC 5/16, p. 1)*.

That was just one of four large settlements involving OCR and academic health systems last year. In 2016, the University of Mississippi Medical Center paid $2.75 million, Oregon Health and Sciences Center ran close behind with a $2.7 million agreement and New York Presbyterian paid $2.2 million for the unauthorized filming of patients in its emergency room, one of whom was shown dying while his unsuspecting family members waited in another room. His widow recognized his voice and the circumstances (his face had been blurred) when she later saw the show on television.

That settlement was not the first time New York Presbyterian made an OCR payment. Two years earlier, New York Presbyterian paid $3.3 million and Columbia University separately paid $1.5 million for their roles in the breach of protected health information (PHI) from a shared IT system that ended up on the internet.

The Memorial Hermann settlement is OCR's eighth to be announced so far this year. These agreements have brought the agency a total of $16.7 million in financial penalties. If the pace of enforcement continues, OCR is likely to exceed the record $24.5 million it collected from 13 organizations in 2016.

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tives." According to the court documents, MMC didn't know this was happening.

The case involved the HHS Office of Inspector General, the announcement said. David Boling, a spokesman for the U.S. attorney, said MMC has "no current enforcement action pending" against it. When asked how the fraud was uncovered, he referred questions to MMC.

But MMC officials declined to answer *RRC*'s questions on the case, stating that it was "still ongoing" because McCain-Davis has not yet been sentenced.

"We have been working with the U.S. Attorney's office throughout the investigation and we support the decision of the court," MMC spokeswoman Janet Caldwell said in an email.

Reached by phone, McCain-Davis' attorney, Eileen Parrish, told *RRC* she had no comment.

No details in the settlement provide any insights into the source of the funds that McCain-Davis paid to herself, such as whether they came from NIH research projects. The announcement is simply titled "Former Meharry Medical College Employee Pleads Guilty To Theft Of Federal Program Funds." The court documents say only that NIH paid MMC "more than $10,000 in federal funding for each of calendar years 2009-2013."

According to a Jan. 1 charging document, McCain-Davis' "scheme to defraud and unlawfully enrich [herself] consisted of three components: (1) submitting to MMC false invoices in the name of entities created, controlled or operated by McCain-Davis for services that were never provided; (2) submitting to MMC false reimbursement requests for expenses never incurred by McCain-Davis on behalf of MMC; and (3) intercepting checks payable to other MMC employees and forging the employees' signatures onto those checks."

McCain-Davis acknowledged that she used the names "TK Enterprises," "Elizabeth Pearson, Inc.," and "Alexis Catering" on invoices, even though "those companies were not legitimate vendors of MMC, and were not entitled to receive funds from the college."

In 2009, for instance, McCain-Davis "submitted to MMC a false reimbursement request seeking payment for costs associated with attending a conference in Dallas, Texas that [she] did not attend." McCain-Davis collected $1,443.15 "as payment for the reimbursement request."

OCR Snags Another Academic Health System, continued

Although no research data were implicated in the Memorial Hermann settlement, its broad and basic lesson applies to universities and others that may handle protected health information, namely that even if the name of the person associated with the PHI is reported in the news media and is shared with law enforcement officials who may also disclose the name, the CE itself must not disclose PHI unless it has explicit authorization from the person, be he or she a research subject or a patient.

In this instance, the woman's arrest made national headlines and involved statements by Memorial Hermann using her name, including as part of the title of a statement issued as a PDF. In announcing the settlement, OCR Director Roger Severino said that use alone was a "clear" HIPAA violation and that senior management should have known better.

Memorial Hermann was in compliance when it shared the patient's PHI with law enforcement, but not when it "subsequently published a press release concerning the incident in which [Memorial Hermann] senior management approved the impermissible disclosure of the patient's PHI by adding the patient's name in the title of the press release," Severino said in a statement.

He added that the system "failed to timely document the sanctioning of its workforce members for impermissibly disclosing the patient's information."

This is the third settlement OCR has announced that centers on inappropriate disclosures to the news media. The first was a 2013 settlement with a health system that owns an Arizona hospital whose executive discussed a patient by name with staff through an internal email. Although the woman had given press interviews, the hospital never obtained authorization to release her name. The system paid just $275,000 to settle that case.

As noted, one of New York Presbyterian's settlements hinged on this issue as well. At the time, OCR issued an FAQ on disclosures to the media. See http://tinyurl.com/k5fqvbj.

The new settlement "reminds us that organizations can readily cooperate with law enforcement without violating HIPAA, but that they must nevertheless continue to protect patient privacy when making statements to the public and elsewhere," Severino said.

Link: http://tinyurl.com/n46x56

Further, 125 of an unspecified type of "workbook" were billed to MMC under the name of TK Enterprises, for $3,031.25.

"The funds obtained by McCain-Davis' fraudulent scheme were typically deposited into bank accounts under the control of McCain-Davis and/or her close relative," according to the plea agreement.

McCain-Davis' case calls to mind one involving Northwestern University, which resulted in separate settlements for allegations of the False Claim Act by Northwestern itself and by a principal investigator, Charles Bennett. In 2013, Northwestern paid $2.93 million to resolve the allegations, and a year later, Bennett paid $475,000 to resolve "identical claims" brought against Northwestern *(RRC 12/14, p. 4)*.

Northwestern denied the government's allegations that NIH cancer research grants were used for unallowable costs. Bennett, according to the government, "submitted false claims under research grants" from NIH.

The settlement covered improper claims that Bennett submitted for reimbursement from the federal grants for professional and consulting services, food, hotels, travel, conference registration fees, and other expenses that benefited Dr. Bennett, his friends, and family from Jan. 1, 2003, through Aug. 31, 2010. Bennett also denied wrongdoing.

Link: http://tinyurl.com/kafozsc ✧

New GSI Policy Causes Anxiety

continued from p. 1

Information about the GSI has been limited and available through various forums. The May 2 stakeholder phone call, followed the same day by a statement from NIH Director Francis Collins and a post from Lauer on his Open Mike blog, marked the first time agency officials discussed the new GSI policy. Lauer also addressed the GSI during a meeting of the Federal Demonstration Partnership (FDP) held in Washington, D.C., on May 11. Collins briefly touched on the GSI in response to a question from a member of Congress during an appropriations hearing on May 17.

NIH's action is a response to a complex and interwoven set of trends buffeting the agency and the research community—and a demand from Congress. These include the aging biomedical workforce, increasing scarcity of NIH funds and what agency leaders refer to as diminishing returns once a PI hits three awards. A startling statistic is that today, 40% of NIH funding goes to just 10% of agency-supported investigators.

Imposing the GSI won't cure all these ills, and it will need to be used in concert with other efforts, NIH officials say.

As Collins explained in his May 2 statement, the GSI "is a measure of grant support that does not solely focus on grant money, since differing areas of research inherently incur differing levels of cost. Instead, GSI assigns a point value to the various kinds of grants based on type, complexity, and size."

His announcement added that "[a]pplications for NIH-funding that will support researchers who have GSIs over 21 (the equivalent of 3 single-PI R01 awards) will be expected to include a plan in their applications for how they would adjust those researchers' existing grant load to be within the GSI limits if their application is awarded."

Community Input Sought

The GSI has its origins in a concept called the "research commitment index," which Lauer discussed at an FDP meeting earlier this year *(RRC 2/17, p. 4)*. NIH has renamed the commitment index the GSI.

As Lauer had previously explained in a Jan. 26 blog post, the commitment index assigned a score of seven to RO1s and a six if the investigator was a co-PI. However, NIH has not released the individual scores that go into the GSI.

About a week after the GSI was announced, a note was placed on Lauer's blog post from January about the commitment index, cautioning that "the table used on this page does not reflect the finalized Grant Support Index values" and that "[c]ommunity input will be used in developing the final" GSI.

Still, the 21-point award cap in the GSI would equal three R01s, if valued at seven points, the same calculation in the commitment index.

While Lauer participated in the stakeholder call, most of the explanation and answers to questions were provided by NIH Principal Deputy Director Larry Tabak.

The basic outlines of the GSI policy have been determined, but NIH "hasn't yet made any final decisions about other types of awards" besides RO1s and how they would be measured as part of the index, Tabak said.

He promised that NIH's "approach is going to be measured but forward, and that will give us an opportunity to assess [the policy] for any perhaps unintended consequences that we have not yet been able to identify."

As far as when the GSI would go into effect, Tabak and Lauer have stressed that no current grants or ap-

plicants will be defunded, and the GSI would kick in "when the investigator who is over a GSI 21 submits their next application," Tabak said.

However, unless grantees—and institutions—are given their specific GSI scores in advance, there may not be much time to prepare.

The GSI "will be calculated automatically by eRA and so we will not be placing additional administrative burden on grantee institutions," Tabak said, referring to NIH's electronic research IT system. "Depending upon final details of implementation, we estimate that a GSI limit of 21 would affect only about 6% of NIH funded investigators." He said new awards "will be used to [support] the pool of investigators conducting NIH research and will improve the stability of enterprise."

NIH wants to flesh out the details of the policy following discussions with the "stakeholder community." Institutions should "tune in" to upcoming high-level NIH meetings, such as the Council of Councils and the Advisory Committee to the Director (ACD) of NIH, Tabak said. The meetings of both are usually webcast.

The council's next meeting is May 26. For information, see https://dpcpsi.nih.gov/council/futuremeetings. The ACD meets June 8–9. See https://acd.od.nih.gov.

Tabak said the timeline "has not yet been finalized," but NIH is "considering implementing [the policy] for applications to be submitted in September 2017, which would translate to council considerations for the May-June time period of 2018."

It appears that NIH's institutes and centers will also have some input into carrying out the GSI policy. They will "stress the message that this will be a trans-NIH effort," Tabak said. "Each institute might approach certain aspects of this in a slightly different way."

Committed Effort May be Irrelevant

In response to a question from a stakeholder, Tabak said the GSI would exist separate and distinct from effort—the amount of a PI's time that is devoted to a single project.

"If you are the PI of an award, it will be assigned a certain number of points commensurate with the type of award mechanism it is. We are not modifying or moderating it in any way. At least that's the current thinking," Tabak said.

But other aspects are not certain. During his FDP presentation, Lauer devoted nearly his entire remarks to trends in funding, barely mentioning the GSI until the last minutes of his talk. But during a question-and-answer part of the presentation, the audience peppered Lauer with queries about the GSI.

Lauer explained that NIH must address the issue of too many deserving funding applications and too few dollars, a subject he has spoken of previously *(RRC 6/16, p. 3)*.

He also brought up details such as that the average age of a first-time NIH awardee is 42, compared to 35 in 1980. Lauer showed charts demonstrating how investigators older than 60 ("late stage") now account for approximately 25% of those receiving research project grants (of which RO1 is one) and "other select activities," compared to 10% in 2000.

He discussed research by NIH, published in December, showing the difficulty that scientists with one grant are having obtaining a renewal or a second grant, a situation that can be career-threatening or even ending. This is happening to "mid-career" investigators, aged 45 to 60.

Some PIs Are 'Struggling'

When NIH realized that the age for a first grant was creeping up, it instituted special programs for early-stage investigators, efforts that have seen their success rates grow fairly stable at 30 to 35% of the total.

"Now we are seeing the beginnings of concerns about our losing our mid-career investigators," Lauer said at the FDP meeting. "These are the people whom you've invested your startup efforts in, you've brought them on board, you gave them seed money, you helped them get their first grant. They may be doing perfectly fine work, and yet they're really struggling to keep going."

Lauer said the discussion need not be a choice between whether to "concentrate [funding] in a relatively small number of laboratories" versus funding "across a very large swath of the sciences." NIH, he said, can "do both things." He noted that NIH does "big science" with projects such as the Cancer Moonshot and the Precision Medicine Initiative. "The question is: how do you find the right balance?" Lauer said.

NIH needs to address the state of "hypercompetition, which is getting worse and worse and worse. And so this means that a number of very highly talented, skilled, very-well-trained scientists…we're going to lose them" if they don't receive funding, Lauer said.

The agency doesn't want to simply impose a cap, for example, of $1 million per investigator or lab because then expensive animal research and clinical trials wouldn't be funded.

"What we attempted to do was come up with some kind of measure of support that a scientist gets that doesn't penalize them for doing more expensive work but is not as simplistic" as a cap, he said.

Like Tabak, Lauer said he could not offer specifics on co-PIs, subawards and other types of grants. The initiative is "very much a work in progress" and NIH is "still trying to figure out how to calibrate this," he said.

Those who wish to weigh-in on the GSI can comment on Lauer's blog post, which has already "broken all records," Lauer said. As of *RRC*'s deadline, the post had garnered more than 350 comments (see http://tinyurl.com/lhjynkq).

Lauer joked that generally the type of posts that get commenters the most "excited" are about peer review. "We found out that there's actually something else other than peer review" that piques attention, he said.

At the very least, NIH has "succeeded in stimulating a conversation" about the scientific workforce of the future and whether NIH is making awards "as smartly as we possibly can," Lauer said.

As noted earlier, Collins also spoke about the GSI, responding to questions posed by Rep. Chuck Fleischmann, R-Tenn., during an "oversight" hearing of the HHS subcommittee of the House Appropriations Committee on advances in biomedical research.

Collins said NIH will be taking steps to monitor the policy as it goes into effect to see "that we don't cause harms" and will include an "exceptions process." NIH, he said, does not "want to penalize people who are doing public service, as for instance with a training grant or running a center…we're deep into that kind of sophisticated conversation." (See http://tinyurl.com/llxyu9d.)

Link: http://tinyurl.com/m7q2d9g ✧

In This Month's E-News

The following are summaries of news transmitted to RRC *subscribers this month in email issues, the date of which is indicated in parentheses following each item. Weekly email and monthly print issues of* RRC *are archived on your subscriber-only website. Please call 888-580-8373 or email service@hcca-info.org if you require a password to access* RRC*'s subscriber-only website or are not receiving weekly email issues of the newsletter.*

◆ **Following a 2016 inspection, the Food and Drug Administration (FDA) asked Merrill Benson, M.D., a professor in the Department of Pathology and Laboratory at Indiana University, for details on how he would prevent future research lapses from occurring similar to issues for which he was cited.** These include the failure to conduct timely blood and urine tests and the enrollment of an ineligible subject. FDA said the inspection occurred "between October 11, 2016, and November 10, 2016." The agency did not describe the type of research being conducted. In the March 20 letter, posted May 8, FDA said it was seeking additional responses from Benson beyond the corrective action plan he submitted following the inspection. *(5/18/17)*

◆ **The Office of Management and Budget (OMB) has issued a new compliance date for changes in procurement requirements in the uniform guidance (UG) for federal awards, granting "a grace period of one additional fiscal year," as described in a notice in the May 17 Federal Register.** The delay applies to procurement standards in 2 CFR 200.317 through 200.326. The compliance date for most universities is now July 1, 2018, according to the Council on Governmental Relations (COGR). The UG was first published in 2014 as a means of standardizing policies and reducing administrative burdens on awardees *(RRC 7/14, p. 1)*. But universities have been disappointed with many of the provisions, particularly related to procurement. A delay, which is the second to be granted, has been awaited for many months as the new requirements were set to go into effect July 1 *(RRC 7/16, p. 5)*. COGR officials and others are still working with OMB to make revisions in the procurement provisions related to conflict of interest and other requirements. *(5/18/17)*

◆ **At a hearing before the House Oversight Subcommittee of the Appropriations Committee on May 17, NIH Director Francis Collins said 44 chimpanzees were transferred last year to Chimp Haven but that approximately 350 have yet to be retired.** Calling the process "challenging," Collins said NIH cannot send more than nine per month because of the time required to socialize the animals, who are moved in social groups, and that retirement is not being delayed by lack of funds. Collins said he spends "a lot of my own personal time trying to be sure that we are moving away from a time where chimpanzees were utilized for research," with the goal of full retirement. NIH agreed to retire the chimpanzees in 2013 and was criticized last year by the Government Accountability Office

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(GAO) for failing to have a comprehensive plan to carry that out. After the GAO report, NIH said retirement could take up to 10 years *(RRC 9/16, p. 6).* Other discussions at the hearing addressed the need for increases in NIH's budget and to maintain funding for administrative or indirect costs to awardees. Showing a list of private funders' administrative contributions, Rep. Andy Harris, R-MD, however, repeated his position that the federal government should not pay more than such organizations, an opinion he voiced in March. Some members of Congress have expressed alarm that the Trump administration has proposed reducing NIH's fiscal year (FY) 2018 budget by 20%, a feat HHS Secretary Tom Price testified could be achieved through cuts to administrative payments *(RRC 5/17, p. 1).* Trump proposed a similar cut for the remaining months of FY 2017, but Congress instead voted to increase NIH's funding by $6 billion, or 6.2% above FY 2016 levels. *(5/18/17)*

◆ **A five-paragraph, internal memo from the HHS chief of staff to agency division leaders to "restate the…long-standing policy" requiring prior approval before employees speak to Congress has raised the ire of Sen. Chuck Grassley, R-Iowa, and Rep. Jason Chaffetz, R-Utah, chairs of the Senate Judiciary and House Oversight and Government Affairs Committees, respectively.** "Federal employees will most certainly read this instruction as a prohibition against direct communications with Congress without permission. As such, it is potentially illegal and unconstitutional, and will likely chill protected disclosures of waste, fraud, and abuse," they said in their letter, issued a day after the May 3 HHS memorandum. Grassley and Chaffetz requested HHS provide "specific written guidance to all agency employees making them aware of their right to communicate directly and independently with Congress. Such guidance should inform employees of the whistleblower protections that apply, and make clear that the agency will not retaliate against any employee who chooses to exercise these rights." The committee chairs are also seeking from HHS "all documents and communications referring or relating to this directive as soon as possible but no later than May 18." The HHS directive is just one example of changes affecting federal agencies since Trump took office (*RRC 5/17, p. 1*). In related news, the Environmental Protection Agency and the Department of Interior have reportedly told some members of advisory committees they will not be reappointed and future meetings have been suspended pending a review. *(5/11/17)*

◆ **After three years of preparation, the Treasury Department on May 9 launched a new public website in compliance with the 2014 Digital Accountability and Transparency (DATA) Act, which expanded reporting of government expenditures, including grants and contracts to universities and other institutions.** The act builds on the Federal Funding Accountability and Transparency Act *(RRC 2/15, p. 7)*. Established in a "beta" version, the website "for the first time, links spending data to awards distributed by the government," the department said. The website address is https://beta.usaspending.gov. "Data from the current USAspending.gov will be transferred to the new site, along with additional functionality, throughout the summer on a rolling basis," reads a notice on the page. *(5/11/17)*

◆ **After a vote on April 27 by the Senate Health, Education, Labor and Pensions Committee, the full Senate will consider Dr. Scott Gottlieb to be commissioner of the Food and Drug Administration (FDA).** In related news, President Trump has nominated Dr. Brett Giroir, formerly the executive vice president and CEO of the Health Science Center at Texas A&M University, to be the HHS assistant secretary for health (ASH). Giroir, who was nominated on April 21, is the current CEO of a Texas A&M spin-off pharmaceutical research firm, ViraCyte, Inc. No dates have yet been set for votes on Gottlieb or Giroir. There has not been a confirmed ASH since Howard Koh, who resigned in 2014 (*RRC 2/14, p. 9*). If confirmed, Giroir would oversee 12 HHS agencies, including the Office for Human Research Protections (OHRP) and Office for Research Integrity (ORI), both of which are experiencing challenges. OHRP, which enforces regulations regarding clinical trials, began slowing down enforcement at the start of the Obama administration (*RRC 4/16, p. 10*). It has not posted a determination letter since October. Since Director Kathryn Partin arrived in December 2015, ORI has seen a departure of the head of its education division and the defection of a number of staff who investigate allegations of research misconduct. In 2016, ORI made just seven findings of fabrication, falsification and plagiarism, less than half the typical annual number (*RRC 1/17, p. 1*). It has made no findings since August of last year. *(5/4/17)*